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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,447	08/17/2006	Osamu Tajima	049441-0144	2302
22428 7590 05/30/2007 FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			EXAMINER CHEN, CATHERYNE	
			ART UNIT 1655	PAPER NUMBER
			MAIL DATE 05/30/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/552,447	<b>Applicant(s)</b> TAJIMA ET AL.	
	<b>Examiner</b> Catheryne Chen	<b>Art Unit</b> 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 April 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 1-26, 29 and 30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27 and 28 is/are rejected.
- 7) ☒ Claim(s) 27 and 28 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>Aug. 17, 2006, Oct. 6, 2005</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Currently, Claims 1-30 are pending. Claims 27-28 are examined on the merits.

#### ***Election/Restrictions***

Applicant's election without traverse of group II (Claims 27-28) in the reply filed on April 23, 2007 is acknowledged.

Claims 1-27, 29-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on April 23, 2007.

#### ***Claim Objections***

Claims 27 and 28 are objected to because they all depend from non-elected Claims 1-4. If Claims 1-4 were cancelled, a rejection under 35 U.S.C. 112, second paragraph would be required. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27 and 28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inhibition of the reduction of bone mineral density, does not reasonably provide enablement for prevention of bone mineral density reduction. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

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Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and the breadth of the claims. In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Applicant's claims are broadly drawn to a composition that is able to prevent bone mineral density reduction. In order to be enabled for prevention of a condition, applicant must demonstrate that the invention is able to prevent the condition each and every instance of that condition. Applicant's specification does not set forth any evidence that the claimed product is able to prevent bone mineral density reduction for all potential causes of bone mineral density reduction. In addition, the art teaches bone mineral density reduction prevention is not accepted as possible because many risk factors such as diet, age, race and family history cannot be controlled (see <http://diglib.tums.ac.ir/pub/magmng/pdf/2417.pdf> ). Because applicant's specification does not show prevention of bone mineral density reduction and the art acknowledges that prevention is not currently possible, a person of ordinary skill in the art would be forced to experiment unduly in order to determine if applicant's invention actually functions as claimed. Therefore, the claims are not considered enabled for the prevention of bone mineral density reduction.

***Claim Rejections - 35 USC § 102***

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 27 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Erdelmeier et al. (WO 03/014287 A1 with US 2005/0042318 A1 as translation).

Erdelmeier et al. teaches extracts from hop as treatment for osteoporosis (paragraph 0004), where xanthohumol is extracted with ethanol (paragraph 0010), polar solvents, preferably hot water (paragraph 0012), alkane or supercritical carbon dioxide, subsequent extraction using water and alcohols (paragraph 0018).

Claims 27 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Tobe et al. (5679716).

Tobe et al. teaches therapeutic agent for osteoporosis with xanthohumol in hop extracts (column 1, lines 14, 28), which can be prepared from acetone percolation, eluted with acetic acid and methanol (column 3, lines 15-36).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erdelmeier et al. (WO 03/014287 A1 with US 2005/0042318 A1 as translation).

Erdelmeier et al. teaches extracts from hop as treatment for osteoporosis (paragraph 0004), where xanthohumol is extracted with ethanol (paragraph 0010), polar solvents, preferably hot water (paragraph 0012), alkane or supercritical carbon dioxide, subsequent extraction using water and alcohols (paragraph 0018). However it does not teach isoxanthohumol.

It is obvious to substitute isoxanthohumol for xanthohumol because isomers are considered obvious to substitute for one another (see MPEP 2144.09). Since isomers are structurally similar, an artisan of ordinary skill would reasonably expect that the isomers would function equivalently to each other. This reasonable expectation of success provides the motivation for the substitution.

Claims 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens et al. (J. Chromatography A, 1999, vol. 832, pages 97-107) and Tobe et al. (US 5679716).

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Stevens et al. teaches hops extracted to obtain xanthohumol and isoxanthohumol with methanol (Experimental, pages 98, 99). However it does not teach the use for inhibiting bone mineral density reduction.

The reference does not specifically teach that hop extracts in particular can be used to treat bone mineral density reduction. However, a person of ordinary skill in the art would reasonably expect that hops extracts could be used to treat bone mineral density reduction based on the broad disclosure by Tobe et al. that xanthohumol from hop extracts has bone resorption inhibiting activity and is useful as a therapeutic agent for osteoporosis (abstract). Based on this reasonable expectation of success, a person of ordinary skill in the art would be motivated to use hop extract to treat bone mineral density reduction.

### ***Conclusion***

No claim is allowed.

### ***Contact Information***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catheryne Chen whose telephone number is 571-272-9947. The examiner can normally be reached on Monday to Friday, 9-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Catheryne Chen  
Patent Examiner  
Art Unit 1655

  
SUSAN COE HOFFMAN  
PRIMARY EXAMINER